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10/26/00
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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

JASON ERIC BENSON, Plaintiff	:	CIVIL ACTION NO. 1:CV-00-1229
	:	(JUDGE CALDWELL)
vs.	:	
	:	(MAGISTRATE JUDGE BLEWITT)
THOMAS DURAN, et al., Defendants	:	

FILED
SCRANTON
OCT 26 2000
PER _____ DEPUTY CLERK

PLAINTIFF'S OPPOSITION TO DEFENDANT STEINOUR'S MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT

AND NOW, comes plaintiff Benson, Jason E., and files this Opposition to Defendant Steinour's, Motion to Dismiss Plaintiff's Amended Complaint pursuant to F.R.Civ.P. 12(b)(6), and states as follows:

1. The defendant Steinour, alleges that plaintiff has no cause for action because he did not act under color of state law, he did not act with deliberate indifference to plaintiff's serious medical needs, and that palintiff is unable to prove any set of facts in support of his claims which would entitle him to relief.

2. The defendant admitts being sued in "his individual capacity," Id., at Defendant's Motion to Dismiss, (¶2). The United States Supreme Court reason in Farmer v. Brennan, "[P]ersonal participation is an essential allegation in a §1983 Claim." Id., at 114 S.Ct. 1977 (1994); Stickler v. Waters, 989 F.2d 1381 (1993); Bennett v. Passic, 545 F.2d 1260,1262-63 (10th Cir.1976).

3. The phrase "[I]ndividual Capacity", means (a specific persons sufficiency). Unlike, when a person is sued in their "[o]fficial Capacity," and cloaked with the immunity of a Sovereign Entity, or

Municipalities, et cetera, et cetera. In essence, plaintiff did not specifically state, as one must, that Gettysburg General Hospital, is also a defendant.

4. Therefore, it's arguably incorrect for the defendant to cite Mutope v. Edgar, et al., Civil No. 3:CV-98-1179, as an issue that is factually the same as the instant matter. In Mutope, the private entity hospital moved for dismissal from claims under §1983,where Plaintiff was brought to the hospital Emergency Department by police following his arrest. The Court determined that Good Samaritan did not have Status as a State actor, and dismissed the §1983 claims(Id).

5. In that action, the Honorable Judge Kosik, in his Order and Memorandum of Law, stated: "Named as defendants are: Randall Edgar: Lt.Klinger; M.Barrett; Officers Spitler and MacNicholas; the Lebanon City Police Department; Raiger, apparently employed at the Lebanon County Correctional Facility; Dr. James Keller;[1] and **Good Samaritan Hospital**.[2] See Def.,Steinour's Motion to Dismiss exhibit "B,pg.2".

6. There are three tests for ~~XXX~~ detecting the presence of action under color of state law; only one is applicable to this action: the "close nexus test,...[wherein] the inquiry is 'whether there is a sufficiently close nexus between the State and the challenged action... so that the action...may be fairly treated as that of the State itself."

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1. It is not known whether or not Mutope, sued Dr. Keller, in official capacity or individually. More likely, he sued officially.

2. Mutope, is [n]ot identical to the instant action, on the grounds that, plaintiff in this action did not sue Gettysburg General Hospital.

Klavan v. Crozer Chester Medical Center, 60 F. Supp.2d 436,441-42(E.D. Pa.1999). Please be mindful that the latter case was against a Medical Center; likewise, was Mutope's, action.

7. In order for the plaintiff to establish a violation of the Eighth Amendment based on the alleged denial of proper medical care, an inmate must demonstrate a deliberate indifference to a serious medical need. Estelle v. Gamble, 429 U.S. 97 (1976). Further, the Court in Brown v. Borough of Chambersburg, reasoned that: "[A]s long as a physician exercises professional judgment his behavior will not violate a prisoner's constitutional rights." Id. at, 903 F.2d 274,278 (3d Cir.1990). At the time of this incident, plaintiff was 22 years old. On June 4th 1999, def., Long, dicontinued plaintiff's anti-convulsant medication. See exhibit "B'. Defendant Long, works as a Medical Doctor at the State Correctional Institution at Smithfield and Def., Long, is well aware of plaintiff's seizures. However, Def., LOng, choose to ignore the fact that another Defendant, Ellien, had prescribed "Imipramine(Tofranil), and Ativan for plaintiff despite the potential harm the drugs would cause. See exhibit "C"

8. The "Physician's Desk Reference, 1994 Supplement, with respect to anti-convulsants (Dilantin): "[W]arning, abrupt withdrawal of phenytoin in epileptic patients may precipitate status epilepticus." See exhibit "D". Likewise, in the reference, there are warnings about the drug Tofranil(Imipramine), which state: "[E]xtreme caution should be used when this drug is given to: 'patients with a history of seizure disorder because this drug has been shown to lower the seizure threshold!" See exhibit "D-1". The same goes for the drug Ativan. Nonetheless, Def., Steinour, saw plaintiff on 8/27/99, and after receiving from the

Exhibit "B"

PHYSICIAN'S ORDERS

Benson JASON
DS6483
9-27-76
SCISm.

Drug Allergies:
NKA

Self-Medication Program ☐ Yes ☐ No

Date/ Military Time	Prob #	DO NOT USE THIS SHEET UNLESS A RED NUMBER SHOWS
0910 4-28-99		① [illegible]
4-28	[illegible]	
		S. CRAIG HOFFMAN PA - C
6/4/99 0915	A	① D/c Dilantin
6-4-99 0920		RONALD A LONG, M.D.
6-8-99 1515	A	① Cont on seizure clinic
		R E McMullen PA-C — RAY McMULLEN, PA-C WHS
6/8/99		
7-23-99		[illegible] TST PPD [illegible] ID
		[illegible] DR. MIGUEL SALOMON M.D.
		DR. MIGUEL SALOMON M.D.

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PLEASE USE BALL POINT PEN ONLY

Exhibit "C"

PHYSICIAN'S ORDERS

Inmate Name: Jason Berson

Inmate Number: DS 6483

DOB: 9-27-76

Institution: Smithfield C

Drug Allergies: NKA

Self-Medication Program ☐ Yes ☑ No

DO NOT USE THIS SHEET UNLESS A RED NUMBER SHOWS — 1

Date/ Military Time	Prob #	
7-27-99	6	① Next appointment in 1 month
1615 hrs		② Ativan 1mg PO q 6 hrs PRN anxiety attack:
		max 2 doses/day · max 6 doses/week, for 1 month
		③ Begin Imipramine 50mg PO hs daily, through 3 Aug '99
		④ On 4 Aug 99 - increase Imipramine to 75mg PO hs,
		daily, through 10 Aug 1999
		⑤ On 11 Aug 99 - increase Imipramine to 100mg PO hs,
		daily for 5 months
	✓	⑥ On/about 19 Aug 1999 - obtain Tofranil (Imipramine
		+ desipramine) blood level in AM.
		William F. Eleirod MD
[illegible] 7/27/99 2000		

Barb Grove, L.P.N.

Received JUL 27 1999 SCI-Smithfield Medical Records Department

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Filed JUL 2 1999 SCI-SMITHFIELD Medical Records Dept

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Exhibit "D"

Parke-Davis—Cont.

COLY-MYCIN® S OTIC ℞

[c*ˈlī-mȳ ˈcĭn s ō ˈtĭc]

(…eomycin and Hydrocortisone
…n sulfate—neomycin
…—thonzonium
bromide—hydrocortisone acetate
otic suspension)

DESCRIPTION

Coly-Mycin S Otic with Neomycin and Hydrocortisone (colistin sulfate-neomycin sulfate-thonzonium bromide-hydrocortisone acetate otic suspension) is a sterile aqueous suspension containing in each ml: Colistin base activity, 3 mg (as the sulfate); Neomycin base activity, 3.3 mg (as the sulfate); Hydrocortisone acetate, 10 mg (1%); Thonzonium bromide, 0.5 mg (0.05%); Polysorbate 80, acetic acid, and sodium acetate in a buffered aqueous vehicle. Thimerosal (mercury derivative), 0.002%, added as a preservative. It is a non-viscous liquid, buffered at pH 5, for instillation into the canal of the external ear or direct application to the affected aural skin.

CLINICAL PHARMACOLOGY

1. Colistin sulfate—an antibiotic with bactericidal action against most gram-negative organisms, notably *Pseudomonas aeruginosa, E. coli.*, and *Klebsiella-Aerobacter.*
2. Neomycin sulfate—a broad-spectrum antibiotic, bactericidal to many pathogens, notably *Staph aureus* and *Proteus* sp.
3. Hydrocortisone acetate—a corticosteroid that controls inflammation, edema, pruritus and other dermal reactions.
4. Thonzonium bromide—a surface-active agent that promotes tissue contact by dispersion and penetration of the cellular debris and exudate.

INDICATIONS AND USAGE

For the treatment of superficial bacterial infections of the external auditory canal, caused by organisms susceptible to the action of the antibiotics; and for the treatment of infections of mastoidectomy and fenestration cavities, caused by organisms susceptible to the antibiotics.

…TRAINDICATIONS

…product is contraindicated in those individuals who …shown hypersensitivity to any of its components, and in herpes simplex, vaccinia and varicella.

WARNINGS

As with other antibiotic preparations, prolonged treatment may result in overgrowth of nonsusceptible organisms and fungi.

If the infection is not improved after one week, cultures and susceptibility tests should be repeated to verify the identity of the organism and to determine whether therapy should be changed.

Patients who prefer to warm the medication before using should be cautioned against heating the solution above body temperature, in order to avoid loss of potency.

PRECAUTIONS

General: If sensitization or irritation occurs, medication should be discontinued promptly.

This drug should be used with care in cases of perforated eardrum and in longstanding cases of chronic otitis media because of the possibility of ototoxicity caused by neomycin.

Treatment should not be continued for longer than ten days.

Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin.

ADVERSE REACTIONS

Neomycin is a not uncommon cutaneous sensitizer. There are articles in the current literature that indicate an increase in the prevalence of persons sensitive to neomycin.

DOSAGE AND ADMINISTRATION

The external auditory canal should be thoroughly cleansed and dried with a sterile cotton applicator.

When using the calibrated dropper:

For adults, 5 drops of the suspension should be instilled into the affected ear 3 or 4 times daily. For infants and children, 4 drops are suggested because of the smaller capacity of the ear canal.

…is dosage correlates to the 4 drops (for adults) and 3 drops …children) recommended when using the dropper-bottle …tainer for this product.

The patient should lie with the affected ear upward and then the drops should be instilled. This position should be maintained for 5 minutes to facilitate penetration of the drops into the ear canal. Repeat, if necessary, for the opposite ear.

If preferred, a cotton wick may be inserted into the canal and then the cotton may be saturated with the solution. This

4 hours. The wick should be replaced at least once every 24 hours.

HOW SUPPLIED

Coly-Mycin S Otic is supplied as:

N 0071-3141-35—5-mL bottle with dropper
N 0071-3141-36—10-mL bottle with dropper

Each ml contains: Colistin sulfate equivalent to 3 mg of colistin base, Neomycin sulfate equivalent to 3.3 mg neomycin base, Hydrocortisone acetate 10 mg (1%), Thonzonium bromide 0.5 mg (0.05%), and Polysorbate 80 in an aqueous vehicle buffered with acetic acid and sodium acetate. Thimerosal (mercury derivative) 0.002% added as a preservative.

Shake well before using.

Store at controlled room temperature 15°–30°C (59°–86°F). Stable for 18 months at room temperature; prolonged exposure to higher temperatures should be avoided.

3141G033

Caution—Federal law prohibits dispensing without prescription.

KAPSEALS®
DILANTIN® ℞

[dī-lăn ˈtĭn "]

(Extended Phenytoin Sodium Capsules, USP)

DESCRIPTION

Phenytoin Sodium is an antiepileptic drug. Phenytoin sodium is related to the barbiturates in chemical structure, but has a five-membered ring. The chemical name is sodium 5,5-diphenyl-2,4-imidazolidinedione.

Each Dilantin—*Extended Phenytoin Sodium Capsule* USP contains 30 mg or 100 mg phenytoin sodium USP. Also contains lactose, NF; sucrose, NF; talc, USP; and other ingredients. The capsule shell and band contain colloidal silicon dioxide, NF; FD&C red No. 3; gelatin, NF; glyceryl monooleate; sodium lauryl sulfate, NF. The Dilantin 30-mg capsule shell and band also contain citric acid, USP; FD&C blue No. 1; sodium benzoate, NF; titanium dioxide, USP. The Dilantin 100-mg capsule shell and band also contain FD&C yellow No. 6; hydrogen peroxide 3%; polyethylene glycol 200. Product *in vivo* performance is characterized by a slow and extended rate of absorption with peak blood concentrations expected in 4 to 12 hours as contrasted to *Prompt Phenytoin Sodium Capsules* USP with a rapid rate of absorption with peak blood concentration expected in 1½ to 3 hours.

CLINICAL PHARMACOLOGY

Phenytoin is an antiepileptic drug which can be useful in the treatment of epilepsy. The primary site of action appears to be *the motor cortex* where spread of seizure activity is inhibited. Possibly by promoting sodium efflux from neurons, phenytoin tends to *stabilize* the threshold against hyperexcitability caused by excessive stimulation or environmental changes capable of reducing membrane sodium gradient. This includes the reduction of posttetanic potentiation at synapses. Loss of posttetanic potentiation prevents cortical seizure foci from detonating adjacent cortical areas. Phenytoin reduces the maximal activity of brain stem centers responsible for the tonic phase of tonic-clonic (grand mal) seizures.

The plasma half-life in man after oral administration of phenytoin averages 22 hours, with a range of 7 to 42 hours. Steady-state therapeutic levels are achieved 7 to 10 days after initiation of therapy with recommended doses of 300 mg/day.

When serum level determinations are necessary, they should be obtained at least 5-7 half-lives after treatment initiation, dosage change, or addition or subtraction of another drug to the regimen so that equilibrium or steady-state will have been achieved. Trough levels provide information about clinically effective serum level range and confirm patient compliance and are obtained just prior to the patient's next scheduled dose. Peak levels indicate an individual's threshold for emergence of dose-related side effects and are obtained at the time of expected peak concentration. For Dilantin Kapseals peak serum levels occur 4-12 hours after administration.

Optimum control without clinical signs of toxicity occurs more often with serum levels between 10 and 20 mcg/ml, although some mild cases of tonic-clonic (grand mal) epilepsy may be controlled with lower-serum levels of phenytoin.

In most patients maintained at a steady dosage, stable phenytoin serum levels are achieved. There may be wide interpatient variability in phenytoin serum levels with equivalent dosages. Patients with unusually low levels may be noncompliant or hypermetabolizers of phenytoin. Unusually high levels result from liver disease, congenital enzyme deficiency or drug interactions which result in metabolic interference. The patient with large variations in phenytoin plasma levels, despite standard doses, presents a difficult clinical problem. Serum level determinations in such patients may be

free phenytoin levels may be altered in p… tein binding characteristics differ from … Most of the drug is excreted in the bile a… lites which are then reabsorbed from the … excreted in the urine. Urinary excretion o… metabolites occurs partly with glomerul… more importantly, by tubular secretion. B… is hydroxylated in the liver by an enzym… saturable, small incremental doses may … stantial increases in serum levels, when t… per range. The steady-state level may be d… increased, with resultant intoxication, fr… dosage of 10% or more.

INDICATIONS AND USAGE

Dilantin is indicated for the control of ton… chomotor (grand mal and temporal lobe)… vention and treatment of seizures occurring… ing neurosurgery.

Phenytoin serum level determinations ma… for optimal dosage adjustments (see Dosa… istration).

CONTRAINDICATIONS

Phenytoin is contraindicated in those pati… persensitive to phenytoin or other hydant…

WARNINGS

Abrupt withdrawal of phenytoin in epilep… precipitate status epilepticus. When, in the… clinician, the need for dosage reduction, di… substitution of alternative antiepileptic m… this should be done gradually. However, i… allergic or hypersensitivity reaction, rapi… alternative therapy may be necessary. In … tive therapy should be an antiepileptic drug… the hydantoin chemical class.

There have been a number of reports sugge… ship between phenytoin and the developm… nopathy (local or generalized) including be… hyperplasia, pseudolymphoma, lymphoma… Disease.

Although a cause and effect relationship ha… lished, the occurrence of lymphadenopath… need to differentiate such a condition fro… lymph node pathology. Lymph node involve… with or without symptoms and signs resem… ness eg, fever, rash and liver involvement… In all cases of lymphadenopathy, follow-up … an extended period is indicated and every … made to achieve seizure control using altern… tic drugs.

Acute alcoholic intake may increase pheny… while chronic alcoholic use may decrease s…

In view of isolated reports associating phen… erbation of porphyria, caution should be ex… this medication in patients suffering from…

Usage in Pregnancy:

A number of reports suggests an association… of antiepileptic drugs by women with epile… incidence of birth defects in children born… Data are more extensive with respect to ph… nobarbital, but these are also the most comm… antiepileptic drugs; less systematic or anec… gest a possible similar association with the… antiepileptic drugs.

The reports suggesting a higher incidence o… children of drug-treated epileptic women ca… as adequate to prove a definite cause and eff… There are intrinsic methodologic problems i… quate data on drug teratogenicity in humans… or the epileptic condition itself may be mor… drug therapy in leading to birth defects. The… of the mothers on antiepileptic medication… infants. It is important to note that anti… should not be discontinued in patients in wh… administered to prevent major seizures… strong possibility of precipitating status e… attendant hypoxia and threat to life. In … where the severity and frequency of the seiz… such that the removal of medication does n… threat to the patient, discontinuation of … considered prior to and during pregnancy… not be said with any confidence that even m… not pose some hazards to the developing e… prescribing physician will wish to weigh… ations in treating and counseling epile… childbearing potential.

In addition to the reports of increased incide… malformation, such as cleft lip/palate and… tions in children of women receiving phen… antiepileptic drugs, there have more recent… a fetal hydantoin syndrome. This consists of… deficiency, microcephaly and mental defic… born to mothers who have received phenyt…

Exhibit D(2)

Skin rash, petechiae, urticaria, itching, photosen-
edema (general or of face and tongue); drug fever;
sitivity with desipramine.
Bone marrow depression including agranulo-
sinophilia; purpura; thrombocytopenia.
testinal: Nausea and vomiting, anorexia, epigas-
diarrhea; peculiar taste, stomatitis, abdominal
k tongue.
Gynecomastia in the male; breast enlargement
rrhea in the female; increased or decreased li-
nce; testicular swelling; elevation or depression
sugar levels; inappropriate antidiuretic hormone
secretion syndrome.
Jaundice (simulating obstructive); altered liver
weight gain or loss; perspiration; flushing; urinary
drowsiness, dizziness, weakness and fatigue;
parotid swelling; alopecia; proneness to falling.
wal Symptoms: Though not indicative of addiction,
cessation of treatment after prolonged therapy may
nausea, headache and malaise.

AND ADMINISTRATION

up to 100 mg/day intramuscularly in divided doses.
al administration should be used only for starting
in patients unable or unwilling to use oral medica-
oral form should supplant the injectable as soon as

dosages are recommended for elderly patients and
nts. Lower dosages are also recommended for outpa-
compared to hospitalized patients who will be under
pervision. Dosage should be initiated at a low level
reased gradually, noting carefully the clinical re-
and any evidence of intolerance. Following remission,
intenance medication may be required for a longer
of time, at the lowest dose that will maintain

OSAGE

have been reported to be more sensitive than adults
ute overdosage of imipramine hydrochloride. An
erdose of any amount in infants or young children,
ly, must be considered serious and potentially fatal.
Symptoms: These may vary in severity depend-
factors such as the amount of drug absorbed, the
the patient, and the interval between drug ingestion
start of treatment. Blood and urine levels of imipra-
ay not reflect the severity of poisoning; they have
qualitative rather than quantitative value, and are
indicators in the clinical management of the

malities may include drowsiness, stupor, coma,
lessness, agitation, hyperactive reflexes, mus-
y, athetoid and choreiform movements, and

abnormalities may include arrhythmia, tachycar-
evidence of impaired conduction, and signs of con-
failure.

ry depression, cyanosis, hypotension, shock, vomit-
pyrexia, mydriasis, and diaphoresis may also be

The recommended treatment for overdosage
yclic antidepressants may change periodically.
it is recommended that the physician contact a
ntrol center for current information on treatment.
CNS involvement, respiratory depression and car-
ythmia can occur suddenly, hospitalization and
rvation may be necessary, even when the amount
is thought to be small or the initial degree of intoxi-
ears slight or moderate. All patients with ECG
lities should have continuous cardiac monitoring
osely observed until well after cardiac status has
to normal; relapses may occur after apparent re-

t patient, empty the stomach promptly by lavage.
unded patient, secure the airway with a cuffed en-
tube before beginning lavage (do not induce eme-
ation of activated charcoal slurry may help reduce
of imipramine.
external stimulation to reduce the tendency to
If anticonvulsants are necessary, diazepam and
may be useful.
dequate respiratory exchange. Do not use respira-
lants.
ld be treated with supportive measures, such as
position, intravenous fluids, and, if necessary, a
agent. The use of corticosteroids in shock is con-
and may be contraindicated in cases of overdosage
antidepressants. Digitalis may increase conduc-
ities and further irritate an already sensitized
If congestive heart failure necessitates rapid
particular care must be exercised.
should be controlled by whatever external
ailable, including ice packs and cooling sponge
essary.
peritoneal dialysis, exchange transfusions
resis have been generally reported as ineffec-
tive because of the rapid fixation of imipramine in tissues. Blood and urine levels of imipramine may not correlate with the degree of intoxication, and are unreliable indicators in the clinical management of the patient.

The slow intravenous administration of physostigmine salicylate has been used as a last resort to reverse severe CNS anticholinergic manifestations of overdosage with tricyclic antidepressants; however, it should not be used routinely, since it may induce seizures and cholinergic crises.

HOW SUPPLIED

Ampuls 2 ml—*For intramuscular administration only*
25 mg imipramine hydrochloride, 2 mg ascorbic acid, 1 mg sodium bisulfite, 1 mg sodium sulfite
Boxes of 10 ....NDC 0028-0065-23

Store between 59°-86°F (15°-30°C).

Note: Upon storage, minute crystals may form in some ampuls. This has no influence on the therapeutic efficacy of the preparation, and the crystals redissolve when the affected ampuls are immersed in hot tap water for 1 minute.

ANIMAL PHARMACOLOGY & TOXICOLOGY

A. *Acute:* Oral LD_{50} ranges are as follows:

Rat	355 to 682 mg/kg
Dog	100 to 215 mg/kg

Depending on the dosage in both species, toxic signs proceeded progressively from depression, irregular respiration and ataxia to convulsions and death.

B. *Reproduction/Teratogenic:* The overall evaluation may be summed up in the following manner:

Oral: Independent studies in three species (rat, mouse and rabbit) revealed that when Tofranil is administered orally in doses up to approximately 2½ times the maximum human dose in the first 2 species and up to 25 times the maximum human dose in the third species, the drug is essentially free from teratogenic potential. In the three species studied, only one instance of fetal abnormality occurred (in the rabbit) and in that study there was likewise an abnormality in the control group. However, evidence does exist from the rat studies that some systemic and embryotoxic potential is demonstrable. This is manifested by reduced litter size, a slight increase in the stillborn rate and a reduction in the mean birth weight.

Parenteral: In contradistinction to the oral data, Tofranil does exhibit a slight but definite teratogenic potential when administered by the subcutaneous route. Drug effects on both the mother and fetus in the rabbit are manifested in higher resorption rates and decrease in mean fetal birth weights, while teratogenic findings occurred at a level of 5 times the maximum human dose. In the mouse, teratogenicity occurred at 1½ and 6½ times the maximum human dose, but no teratogenic effects were seen at levels 3 times the maximum human dose. Thus, in the mouse, the findings are equivocal.

C91-42 (Rev. 2/92)

Dist. by:
Geigy Pharmaceuticals
Ciba-Geigy Corporation
Ardsley, New York 10502

TOFRANIL® ℞
[*toe-fray 'nill*]
imipramine hydrochloride USP
Tablets of 10 mg
Tablets of 25 mg
Tablets of 50 mg
For oral administration

DESCRIPTION

Tofranil, imipramine hydrochloride USP, the original tricyclic antidepressant, is a member of the dibenzazepine group of compounds. It is designated 5-[3-(Dimethylamino)propyl]-10, 11-dihydro-5H-dibenz[b,f] azepine Monohydrochloride.

Imipramine hydrocloride USP is a white to off-white, odorless, or practically odorless crystalline powder. It is freely soluble in water and in alcohol, soluble in acetone, and insoluble in ether and in benzene. Its molecular weight is 316.87.

Inactive Ingredients. Calcium phosphate, cellulose compounds, docusate sodium, iron oxides, magnesium stearate, polyethylene glycol, povidone, sodium starch glycolate, sucrose, talc and titanium dioxide.

CLINICAL PHARMACOLOGY

The mechanism of action of Tofranil is not definitely known. However, it does not act primarily by stimulation of the central nervous system. The clinical effect is hypothesized as being due to potentiation of adrenergic synapses by blocking uptake of norepinephrine at nerve endings. The mode of action of the drug in controlling childhood enuresis is thought to be apart from its antidepressant effect.

INDICATIONS

Depression: For the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than other depressive states. One to three weeks of treatment may be needed before optimal therapeutic effects are evident.

Childhood Enuresis: May be useful as temporary adjunctive therapy in reducing enuresis in children aged 6 years and older, after possible organic causes have been excluded by appropriate tests. In patients having daytime symptoms of frequency and urgency, examination should include voiding cystourethrography and cystoscopy, as necessary. The effectiveness of treatment may decrease with continued drug administration.

CONTRAINDICATIONS

The concomitant use of monoamine oxidase inhibiting compounds is contraindicated. Hyperpyretic crises or severe convulsive seizures may occur in patients receiving such combinations. The potentiation of adverse effects can be serious, or even fatal. When it is desired to substitute Tofranil in patients receiving a monoamine oxidase inhibitor, as long an interval should elapse as the clinical situation will allow, with a minimum of 14 days. Initial dosage should be low and increases should be gradual and cautiously prescribed.

The drug is contraindicated during the acute recovery period after a myocardial infarction. Patients with a known hypersensitivity to this compound should not be given the drug. The possibility of cross-sensitivity to other dibenzazepine compounds should be kept in mind.

WARNINGS

Children: A dose of 2.5 mg/kg/day of Tofranil should not be exceeded in childhood. ECG changes of unknown significance have been reported in pediatric patients with doses twice this amount.

Extreme caution should be used when this drug is given to:

patients with cardiovascular disease because of the possibility of conduction defects, arrhythmias, congestive heart failure, myocardial infarction, strokes and tachycardia. These patients require cardiac surveillance at all dosage levels of the drug;

patients with increased intraocular pressure, history of urinary retention, or history of narrow-angle glaucoma because of the drug's anticholinergic properties;

hyperthyroid patients or those on thyroid medication because of the possibility of cardiovascular toxicity;

patients with a history of seizure disorder because this drug has been shown to lower the seizure threshold;

patients receiving guanethidine, clonidine, or similar agents, since Tofranil may block the pharmacologic effects of these drugs;

patients receiving methylphenidate hydrochloride. Since methylphenidate hydrochloride may inhibit the metabolism of Tofranil, downward dosage adjustment of imipramine hydrochloride may be required when given concomitantly with methylphenidate hydrochloride.

Tofranil may enhance the CNS depressant effects of alcohol. Therefore, it should be borne in mind that the dangers inherent in a suicide attempt or accidental overdosage with the drug may be increased for the patient who uses excessive amounts of alcohol. (See **PRECAUTIONS.**)

Since Tofranil may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as operating an automobile or machinery, the patient should be cautioned accordingly.

PRECAUTIONS

An ECG recording should be taken prior to the initiation of larger-than-usual doses of Tofranil and at appropriate intervals thereafter until steady state is achieved. (Patients with any evidence of cardiovascular disease require cardiac surveillance at all dosage levels of the drug. See **WARNINGS.**)

Elderly patients and patients with cardiac disease or a prior history of cardiac disease are at special risk of developing the cardiac abnormalities associated with the use of Tofranil.

It should be kept in mind that the possibility of suicide in seriously depressed patients is inherent in the illness and may persist until significant remission occurs. Such patients should be carefully supervised during the early phase of treatment with Tofranil, and may require hospitalization. Prescriptions should be written for the smallest amount feasible.

Hypomanic or manic episodes may occur, particularly in patients with cyclic disorders. Such reactions may necessitate discontinuation of the drug. If needed, Tofranil may be resumed in lower dosage when these episodes are relieved. Administration of a tranquilizer may be useful in controlling such episodes.

An activation of the psychosis may occasionally be observed in schizophrenic patients and may require reduction of dosage and the addition of a phenothiazine.

Concurrent administration of Tofranil with electroshock therapy may increase the hazards; such treatment should be

Continued on next page

The full prescribing information for each Geigy product is contained herein and is that in effect as of September 1, 1993.

CERTIFICATE OF SERVICE

I, Jason E. Benson, plaintiff, hereby certify that a true and correct copy of the foregoing document was served upon the following via first class mail:

Jason Kantor, Esquire
Post & Schell, P.C.
240 Grandview Avenue
Camp Hill, PA 17011

Lavery, Faherty, Young & Patterson, P.C.
James D. Young, Esquire
301 Market St., Suite 800
Harrisburg, PA 17108

David L. Schwalm, Esquire
Thomas, Thomas & Hafer
305 North Front Street
P.O.Box 999
Harrisburg, PA 17101

By: _____

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